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10/652,846	08/29/2003	Timothy J. O'Brien	D6020CIP4	5440

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Please find below and/or attached an Office communication concerning this application or proceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/652,846
Filing Date: August 29, 2003
Appellant(s): O'BRIEN ET AL.

Benjamin Aaron Adler
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed January 12, 2009 appealing from the FINAL Office action mailed May 9, 2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Mitsui et al, Eur J Biochem 260: 627-634, 1999.

(9) Grounds of Rejection

The following ground of rejection is applicable to the appealed claims:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 52-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Mitsui et al (of record, Eur J Biochem 260: 627-634, 1999; PTO 892).

Mitsui *et al* teach various nucleotide and amino acid sequences of human type 1 and type 2 neuropsin as well as mouse neuropsin. The reference human type 2 neuropsin is 100 % identical to the claimed TAGD-14 protein variant with an amino acid sequence shown in SEQ ID NO: 75 as well as DNA sequence encoding such protein which includes an intron between exon 2 and 3 (see page 628, Figure 2 as well as DNA encoding such sequence, see Figure 4A at page 360, in particular). Mitsui et al further teach DNA that include an intron 1 sequence between exon 1 and exon 2 and intron 2 sequence between exon 2 and exon 3 wherein the DNA encodes a human neuropsin type 2 that has an amino acid sequence 100% identical to TAG-14 variant having the amino acid sequence of SEQ ID NO: 75 where all of the introns contained the canonical GT/AG dinucleotides at both ends (see nucleic acid sequence at page 630, col. 1, Fig 4A, col. 2, species-specific splicing variant, in particular). Mitsui et al teach a vector such as BAC-TO-BAC comprising regulatory elements necessary for expressing the reference protein in host cell such as insect cell (see page 629, col. 2, Recombinant human neuropsin using a baculovirus expression system, in particular). Thus, the reference teachings anticipate the claimed invention.

(10) Response to Argument

At pages 9-10 of the Brief, Appellants submit that Mitsui et al do not teach the DNA sequence that differs from SEQ ID NO: 6 due to the inclusion of an intron between exon 2 and 3 as recited in claim 52. Mitsui et al do not teach the same vector comprising the regulatory elements necessary for expressing the reference DNA in host cell. The claim recites an isolated DNA that differs from the nucleic acid sequence of SEQ ID NO: 6 due to the inclusion of an intron sequence between exon 2 and exon 3 of SEQ ID NO: 6. Such as DNA encodes a TADG-14 protein variant that has an amino acid sequence of SEQ ID NO: 75. The instant specification discloses that there are differences between TADG-14 and neuropsin differ at the nucleotide level (pg 48, lines 6-14). The TADG-14 mRNA has an additional 491 bases of 5'UTR that were not found in human neuropsin. Also, the nucleotides preceding the poly(A) tail in the 3'UTR are not homologous. In distinct contrast, Mitsui et al disclose a different nucleotide sequence which encodes amino acid sequences of neuropsin. Second, although Mitsui et al teach insertion of exon 2 and exon 3 in the nucleotide sequence of neuropsin (Figure 4A), this nucleotide sequence of neuropsin is not the same as SEQ ID NO: 6. Accordingly, Mitsui et al do not teach the same vector as the instant invention since the TADG-14 and neuropsin differ at the nucleotide level.

In response to the appellants' argument that Mitsui's nucleotide encoding neuropsin (Figure 4A) is not the same as SEQ ID NO: 6, it is noted that claim 52 recites an isolated DNA that *differs* from nucleic acid sequence of SEQ ID NO: 6, not an isolated DNA sequence comprising the nucleotide sequence as set forth in SEQ ID NO: 6. Further, the nucleic acid sequence of Mitsui encodes a protein with an amino acid sequence 100% identical to the claimed sequence shown in SEQ ID NO: 75 (see amino acid sequence in Fig. 2, in particular). Appellants did not dispute that the prior art amino acid sequence shown in Fig. 2 is different from the claimed SEQ ID NO: 75.

```
JOURNAL   Eur. J. Biochem. 260 (3), 627-634 (1999)
   PUBMED   10102990
REFERENCE   2  (bases 1 to 998)
  AUTHORS   Yamaguchi,N. and Mitsui,S.
  TITLE     Direct Submission
  JOURNAL   Submitted (19-NOV-1997) Nozomi Yamaguchi, Kyoto Prefectural
            University of Medicine, Research Institute of Neurological Diseases
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            Tel:+81-75-251-5848, Fax:+81-75-251-5848)
FEATURES             Location/Qualifiers
     source          1. .998
```

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                     /db_xref="taxon:9606"
                     /tissue_type="Brain"
                     /tissue_lib="Brain Placenta"
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                     /product="neuropsin type2"
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                     /db_xref="GI:5672479"
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                     CGGVLVGGNWVLTAAHCKKPKYTVRLGDHSLQNKDGPEQEIPVVQSIPHPCYNSSDVE
                     DHNHDLMLLQLRDQASLGSKVKPISLADHCTQPGQKCTVSGWGTVTSPRENFPDTLNC
                     AEVKIFPQKKCEDAYPGQITDGMVCAGSSKGADTCQGDSGGPLVCDGALQGITSWGSD
                     PCGRSDKPGVYTNICRYLDWIKKIIGSKG"
ORIGIN

Alignment Scores:
Pred. No.:              5.06e-138      Length:         998
Score:                  1708.00        Matches:        305
Percent Similarity:     100.0%         Conservative:   0
Best Local Similarity:  100.0%         Mismatches:     0
Query Match:            100.0%         Indels:         0
DB:                     5              Gaps:           0

          US-10-652-846-75 (1-305) x AB008927 (1-998)

          SEQ 75      1  MetGlyArgProArgProArgAlaAlaLysThrTrpMetPheLeuLeuLeuLeuGlyGly 20
                         ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
          Db         22 ATGGGACGCCCCCGACCTCGTGCGGCCAAGACGTGGATGTTCCTGCTCTTGCTGGGGGGA 81

          Qy         21 AlaTrpAlaAlaCysGlySerLeuAspLeuLeuThrLysLeuTyrAlaGluAsnLeuPro 40
                         ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
          Db         82 GCCTGGGCAGCGTGTGGAAGCCTGGACCTCCTCACTAAGTTGTATGCGGAGAACTTGCCG 141

          Qy         41 CysValHisLeuAsnProGlnTrpProSerGlnProSerHisCysProArgGlyTrpArg 60
                         ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
          Db        142 TGTGTCCATTTGAACCCACAGTGGCCTTCCCAGCCCTCGCACTGCCCCAGAGGGTGGCGA 201

          Qy         61 SerAsnProLeuProProAlaAlaGlyHisSerArgAlaGlnGluAspLysValLeuGly 80
                         ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
          Db        202 TCCAACCCTCTCCCTCCTGCTGCAGGACACTCCAGGGCACAGGAGGACAAGGTGCTGGGG 261

          Qy         81 GlyHisGluCysGlnProHisSerGlnProTrpGlnAlaAlaLeuPheGlnGlyGlnGln 100
                         ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
          Db        262 GGTCATGAGTGCCAACCCCATTCGCAGCCTTGGCAGGCGGCCTTGTTCCAGGGCCAGCAA 321

          Qy        101 LeuLeuCysGlyGlyValLeuValGlyGlyAsnTrpValLeuThrAlaAlaHisCysLys 120
                         ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
          Db        322 CTACTCTGTGGCGGTGTCCTTGTAGGTGGCAACTGGGTCCTTACAGCTGCCCACTGTAAA 381

          Qy        121 LysProLysTyrThrValArgLeuGlyAspHisSerLeuGlnAsnLysAspGlyProGlu 140
                         ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
          Db        382 AAACCGAAATACACAGTACGCCTGGGAGACCACAGCCTACAGAATAAAGATGGCCCAGAG 441

          Qy        141 GlnGluIleProValValGlnSerIleProHisProCysTyrAsnSerSerAspValGlu 160
                         ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
          Db        442 CAAGAAATACCTGTGGTTCAGTCCATCCCACACCCCTGCTACAACAGCAGCGATGTGGAG 501
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Qy        161 AspHisAsnHisAspLeuMetLeuLeuGlnLeuArgAspGlnAlaSerLeuGlySerLys 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        502 GACCACAACCATGATCTGATGCTTCTTCAACTGCGTGACCAGGCATCCCTGGGGTCCAAA 561

Qy        181 ValLysProIleSerLeuAlaAspHisCysThrGlnProGlyGlnLysCysThrValSer 200
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        562 GTGAAGCCCATCAGCCTGGCAGATCATTGCACCCAGCCTGGCCAGAAGTGCACCGTCTCA 621

Qy        201 GlyTrpGlyThrValThrSerProArgGluAsnProAspThrLeuAsnCysAlaGlu 220
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        622 GGCTGGGGCACTGTCACCAGTCCCCGAGAGAATTTTCCTGACACTCTCAACTGTGCAGAA 681

Qy        221 ValLysIleProGlnLysLysCysGluAspAlaTyrProGlyGlnIleThrAspGly 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        682 GTAAAAATCTTTCCCCAGAAGAAGTGTGAGGATGCTTACCCGGGGCAGATCACAGATGGC 741

Qy        241 MetValCysAlaGlySerSerLysGlyAlaAspThrCysGlnGlyAspSerGlyGlyPro 260
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        742 ATGGTCTGTGCAGGCAGCAGCAAAGGGGCTGACACGTGCCAGGGCGATTCTGGAGGCCCC 801

Qy        261 LeuValCysAspGlyAlaLeuGlnGlyIleThrSerTrpGlySerAspProCysGlyArg 280
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        802 CTGGTGTGTGATGGTGCACTCCAGGGCATCACATCCTGGGGCTCAGACCCCTGTGGGAGG 861

Qy        281 SerAspLysProGlyValTyrThrAsnIleCysArgTyrLeuAspTrpIleLysLysIle 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        862 TCCGACAAACCTGGCGTCTATACCAACATCTGCCGCTACCTGGACTGGATCAAGAAGATC 921

Qy        301 IleGlySerLysGly 305
              |||||||||||||||
Db        922 ATAGGCAGCAAGGGC 936
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Mutsui et al further teach genomic DNA sequence encoding the reference human neuropsin 2 that includes an intron sequence between exon 2 and exon 3, as well as acceptor and donor sites at either end of the intron such as the canonical GT/AG dinucleodies at either ends of the intron (see page 630, FIGURE 4A, col. 2, species-specific splicing variant of human neuropsin, page 631, paragraph bridging col. 1 and 2, in particular). Mutsui et al further teach vector such as BAC-TO-BAC baculovirus expression system comprising the reference DNA sequence adapted for expression of the reference protein in host cell such as insect cells (see page 629, col. 2, baculovirus expression system, in particular).

During patent examination, the pending claims must be "given their broadest reasonable interpretation consistent with the specification." The Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005) expressly recognized that the USPTO employs the "broadest reasonable interpretation" standard: The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364[, 70 USPQ2d 1827] (Fed. Cir. 2004). Indeed, the

rules of the PTO require that application claims must "conform to the invention as set forth in the remainder of the specification and the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description." 37 CFR 1.75(d)(1). In re Prater, 162 USPQ 541 (CCPA 1969). See also MPEP § 2111 - § 2111.01.

In the instant case, the specification discloses only two nucleic acid sequences of SEQ ID NO: 6 and the antisense sequence of SEQ ID NO: 72. The nucleic acid sequence of SEQ ID NO: 6 encodes the TADG-14 protein with an amino acid sequence shown in SEQ ID NO: 75. The specification does not describe any DNA that *differs* from nucleic acid sequence of SEQ ID NO: 6 by inclusion of an intron sequence between exon 2 and exon 3 of SEQ ID NO: 6 encodes TADG-14 of SEQ ID NO: 75. Because of the lack of disclosure as to what appellants' intron sequence (intervening sequence) between exon 2 and exon 3 of SEQ ID NO: 6 is look like in the claimed DNA that differs from nucleic acid sequence of SEQ ID NO: 6 (claim 52), the teachings of Mutsui et al is deemed to anticipate the claimed invention (see reference FIG 4A, page 630, in particular).

Further, it is known in the art that intron (intervening sequence) does not translate into protein, these non-coding sections are transcribed to precursor mRNA (pre-mRNA) and some other RNAs (such as long noncoding RNAs), and subsequently removed by a process called splicing during the processing to mature RNA. After intron splicing (i.e. removal), the mRNA consists only of exon derived sequences, which are translated into a protein. If appellants' DNA sequence differs from nucleic acid sequence of SEQ ID NO: 6 and encodes the amino acid sequence of SEQ ID NO: 75, so does the reference nucleotide sequence shown in Fig. 4A that include the introns or the reference nucleotide sequence without the introns as shown in Fig. 2 and still encodes the same protein due to the process called splicing. Because the DNA sequence in claim 52 is not distinct from the reference nucleotide sequence, the reference vector which comprises the reference DNA nucleotide sequence encoding the same protein appears to the same as that of the claimed vector.

With respect to the argument that the TADG-14 mRNA has an additional 491 bases of 5'UTR that were not found in human neuropsin, this is irrelevant because the claims are not drawn to mRNA.

For these reasons, it is believed that the rejection should be sustained.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Phuong Huynh/

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Conferees:

/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1646

/Eileen B. O'Hara/

Supervisory Patent Examiner, Art Unit 1644